K152821

AgaMatrix

AgaMatrix, Inc. • 7C Raymond Avenue • Salem, NH 03079 USA

510(k) Summary

This summary of 510k) substantial equivalence is being submitted in accordance with the requirements of 21 CFR 807.92.

Prepared: 05 September 2013

Submitter: AgaMatrix, Inc.

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NOV 2 0 2013

Contact: William H. McGrail
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Device Name: Product Name: AgaMatrix Health Manager
Common Name: Diabetes Management Software

Device Classification:

Product Code	Classification	Regulation Section	Panel
JQP - Calculator/data processing module for clinical use	Class I	21 CFR 862.2100	75, Clinical Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR 862.1345	75, Clinical Chemistry

Predicate Device:

WaveSense Diabetes Manager application (WDM), K101597

Device Description:

The AgaMatrix Health Manager (app) is an optional software accessory for blood glucose meters manufactured by AgaMatrix. It is a digital logbook and diabetes tool designed to operate using an iPhone or iPod touch. An individual can manually enter blood glucose readings or can download readings directly to the app installed on an iPhone or iPod touch from the AgaMatrix meter by using the AgaMatrix Cable to connect the meter to the connector of the iPhone or iPod touch. The app will allow the user to manually enter carbohydrate, insulin, and weight information.

Users will have the ability to have their data from the AgaMatrix Health Manager automatically uploaded to the AgaMatrix Health Manager cloud portal for back-up. The cloud portal will enable access to the health information in a web browser. Users will have the ability to create and edit their profile, set goals, and download their information as a .csv file.

Labeling:

The AgaMatrix Health Manager User's guide has been updated for clarity to include the images and instructions for the updated user interface, as well as instructions for the added features of user weight tracking, data back-up to the cloud and emailing from the cloud. See Attachment 1 for the AgaMatrix Health Manager User's Guide.

Intended Use:

The AgaMatrix Health Manager App has the same Intended Use as the predicate device (WaveSense Diabetes Manager App in 510(k) premarket notification k101597) except the AgaMatrix Health Manager is intended for use in the home and not in a professional setting. The proposed indications for use are:

The AgaMatrix Health Manager is intended for use in the home to aid individuals with diabetes and their healthcare professionals in the review, analysis and evaluation of blood glucose test results to support an effective diabetes management program. The AgaMatrix Health Manager App is an optional data management software accessory that connects to AgaMatrix blood glucose meters.

The AgaMatrix Health Manager is not intended to provide automated treatment guidance or decisions; nor is it to be used as a substitute for professional healthcare judgment.

Technological Characteristics:

There were no changes to the fundamental scientific technology.

Comparison to Predicate:

Substantial Equivalence Information		
Characteristic	**WaveSense Diabetes Manager App (k101597) Predicate**	**AgaMatrix Health Manager Candidate**
Intended Use	The WaveSense Diabetes Manager App is intended for use in the home and professional settings to aid individuals with diabetes and their healthcare professionals; in the review, analysis and evaluation of blood glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the WaveSense enabled blood glucose meter (BGM) with a mini-USB port. The WaveSense Diabetes Manager allows users to download blood glucose reading automatically from the meter to an iPhone Operating System platform.	Same as predicate except for use in the home only.
Major Features of Device		
Where Used	At home, single patient use and in a professional setting.	Same as predicate except for use in the home only.
Operating system compatibility	Compatible with iPhone Operating System platform	Same
Meter Compatibility	Compatible with WaveSense enabled blood glucose meters (BGM)	Same
Installation	Installation through Apple App Store	Same
Management Tools	Logbook, Statistics, and Trend Charts	Same. Updated user interface. Added feature to track the user's weight.
Data Backup and Storage	Data stored on host Apple Device (locally) and is backed up through iTunes.	Local storage same as predicate, with optional backup to the secure remote server (AgaMatrix Health Manager cloud).
Results and Reports sharing	Email data directly from the app	Same and view and email data from the cloud with authorized login.
User Manual Availability	Accessed through the Application	Same

AgaMatrix Meter Clearance Information:

The AgaMatrix Diabetes Manager User's Guide references the proprietary names of the cleared devices compatible with the application. The table below summarizes the clearance information for all meters referenced in the User's Guide.

Blood Glucose Meter Clearance:

Device Name	510k	Proprietary Names
WAVESENSE KEYNOTE CODELESS BLOOD GLUCOSE MONITORING SYSTEM	K073573	• AgaMatrix/WaveSense Presto Blood Glucose Meter • AgaMatrix/WaveSense Presto Pro Blood Glucose Meter • Up & Up Blood Glucose Meter • Kroger Blood Glucose Meter • Leader Blood Glucose Meter • Meijer Blood Glucose Meter • Top Care Blood Glucose Meter • Diabetes Care Club Presto Blood Glucose Meter • Liberty Blood Glucose Meter • Liberty Codeless Blood Glucose Meter
JAZZ BLOOD GLUCOSE MONITORING SYSTEM	K072413	• AgaMatrix/WaveSense Jazz Blood Glucose Meter • Up & Up Premium Blood Glucose Meter • Kroger Premium Blood Glucose Meter • Leader Premium Blood Glucose Meter • Meijer Premium Blood Glucose Meter • Top Care Premium Blood Glucose Meter

Assessment of Performance:

Verification and validation tests were successfully executed on the AgaMatrix Health Manager. All pre-determined acceptance criteria were met, demonstrating that the device performs appropriately per defined specifications, meets all input requirements, fulfills the device's intended use, and correctly incorporates all required safety mitigations. Results demonstrate substantial equivalence to the predicate system.

A usability study was performed with the AgaMatrix Health Manager (see Attachment 2). Users evaluated data transmission with the AgaMatrix Cable to upload data from a supported AgaMatrix blood glucose meters (Jazz and Presto). Users evaluated uploading, reviewing and managing meter readings in the AgaMatrix Health Manager for ease of use. Users demonstrated the ability to successfully register for a cloud account. Data transmission accuracy and integrity was demonstrated through download comparison between meter to application and application to cloud (csv. file).

Users had to confirm that 100% of the readings downloaded from the meter to the AgaMatrix Health Meter and the study evaluators confirmed that 100% of the readings uploaded to the cloud back up account. The study confirmed that the system is 100% accuracy with respect to data accuracy and integrity when used by the intended population.

Conclusion:

The results the performance assessments demonstrate that the candidate AgaMatrix Health Manager performs in a substantially equivalent manner to that of the predicate. We conclude that the AgaMatrix Health Manager is substantially equivalent the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 20, 2013

AGAMATRIX, INC.
WILLIAM H. McGRAIL
7C RAYMOND AVE
SALEM NH 03079

Re: K132821
Trade/Device Name: AgaMatrix Health Manager
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: October 21, 2013
Received: October 23, 2013

Dear Mr. McGrail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k132821

Device Name: AgaMatrix Health Manager

Indications for Use:

AgaMatrix Health Manager

The AgaMatrix Health Manager is intended for single patient use. It is an accessory to blood glucose monitoring systems to assist in the review, analysis and evaluation of glucose results to aid in diabetes and health management. The AgaMatrix Health Manager collects data from AgaMatrix manufactured glucose meters and allows adding, editing, and viewing additional health data. The AgaMatrix Health Manager is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare advice.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostic Devices and Radiologic Health

510(k) k132821

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